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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,921	05/06/2002	Graham Paul Luscombe	2544/112	5860
2101	7590	10/20/2004	EXAMINER	
BROMBERG & SUNSTEIN LLP			HABTE, KAHSAY	
125 SUMMER STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02110-1618			1624	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,921	LUSCOMBE ET AL.	
	Examiner	Art Unit	
	Kahsay Habte, Ph. D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 24-40 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2004 has been entered.

Response to Amendment

3. Applicant's amendment filed 9/15/04 in response to the previous Office Action (5/11/2004) is acknowledged. Rejections of claims 2-23 under 35 U.S.C. 102(b), (paragraph 4) has been maintained. Rejections of claims 2-23 under 35 U.S.C. §112, second paragraph (items 5a-5c) have been obviated.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 24-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kerrigan et al. (WO 95/07274) with Rothman et al. (US Pat. No. 6,207,699), supplemental. Cited reference teaches the synthesis of benzodioxan derivatives for the treatment of drug abuse, drug addiction and eating disorders (see claims 15 and 19-20) are the same as applicants (see Examples 2, 6, 7, 13, 14, 21 etc.). Said species that are used for the treatment drug abuse, drug addiction and eating disorders are the same as applicants, when applicant's formula I has the following substituents:

U = CH₂; Q = NH-CH₂-piperidinyl, piperidinyl-CH₂-NH (see formula IIa), NH-(CH₂)₃-NH (see formula IIb); and T = methoxy-substituted phenyl, chloro-substituted phenyl or phenyl.

Since said derivatives are the same as applicants, a 102(b) rejection is proper.

Note that the species: N-(7-Chloro-1,4-benzodioxan-2ylmethyl)-1-[1-(2-methoxyphenyl)piperid-4-4yl]methylamine in claim 31 is also the same as Kerrigan's (see Examples 26-27 or claim 12).

Response to arguments

Applicants' arguments filed 09/15/2004 have been fully considered but they are not persuasive.

Applicants argue that (a). Kerrigan does not anticipate the presently claimed subject matter of the instant application, (b). the examiner must provide rationale or evidence (MPEP §706.02, §2112, and §2113), and (c). for anticipation, identical

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invention must be shown in as complete detail as is contained in the patent claim {Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989)}. The examiner disagrees with applicants. The rejection based on Kerrigan et al. (WO 95/07274) is proper, since the compounds used for reducing cravings to food are the same compounds used for treating drug addiction, eating disorders and drug abuse.

Applicants also argue that Kerrigan does not anticipate the presently claimed substances because:

1. Kerrigan does not teach each and every element of the cited invention, nowhere in the list of conditions is the listing for 'cravings to food' explicitly or impliedly.

2. The feature not directly taught by Kerrigan (reducing cravings to food) is also not inherently present in Kerrigan.

3. Kerrigan does not teach the invention 'in as complete detail as is contained in the patent claim'. There is nothing in Kerrigan that explains the relationship between 5-HT receptors and treating eating disorders.

4. Kerrigan is not enabled for a method of reducing cravings to food, since the only data showing biological activity for the compounds of Formula I was done in vitro, with rat brain tissue, to determine K_i values for binding to 5-HT receptors. There is no *in vivo* data, no data in humans. No discussions of how the 5-HT receptors are involved in eating disorders.

The examiner disagrees with applicants' arguments. Kerrigan teaches a method of treating eating disorders and obesity. Note that craving is the essence of food or any kind of addiction. For example, the treatment of drug abuse or a drug addiction is

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directly connected with the craving. According to Rothman et al. (US Pat. No. 6,207,699), there is a direct link between the increase of brain serotonin (5-HT) and the reduction of cravings to food. On column 1 (lines 41-43) "Medications which increase brain serotonin (5-hydroxytryptamine, 5-HT) decrease hunger, cravings for food, especially for carbohydrates and candy (i.e. sweets)." One skilled in the art would understand that the treatment of obesity as taught in Kerrigan arises from a mechanism of reducing cravings to food, as is taught in Rothman et al. Thus, the treatment of obesity as disclosed in Kerrigan would be understood as a method of reducing cravings to food as disclosed in Rothman. This shows that there is a direct relationship between the increase of 5-HT and cravings to food. Thus, this rebuts applicant's argument: "Kerrigan is not enabled for a method of reducing cravings to food.... there is no relationship between 5-HT receptors and eating disorders,... or the feature not directly taught by Kerrigan (reducing cravings to food) is also not inherently present in Kerrigan." Thus, the 102(b) rejection is proper.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kerrigan et al. (WO 95/07274) as applied to claims 24-40 above, and further in view of Rothman et al. (US Pat. No. 6,207,699). Kerrigan et al. teaches the synthesis of benzodioxan derivatives for the treatment of obesity and eating disorders (see claims 15 and 19-20) are almost the same as applicants (see Examples 2, 6, 7, 13, 14, 21 etc.). Said species that are used for the treatment of obesity and eating disorders are almost the same as applicants, when applicant's formula I has the following substituents:

U = CH₂; Q = NH-CH₂-piperidinyl, piperidinyl-CH₂-NH (see formula IIa), NH-(CH₂)₃-NH (see formula IIb); and T = methoxy-substituted phenyl, chloro-substituted phenyl or phenyl.

The only difference between applicants and the prior art is that Kerrigan compounds are not explicitly used for a method of reducing cravings to food, but rather for "obesity". Since Rothman et al. teaches on column 1 (lines 41-43) the relationship of 5-HT receptors with a method of reducing cravings for food, it is obvious to one skilled in the art at the time of the invention was made to use Kerrigan compounds (that are the same as applicants) and use them for a method of reducing cravings to food, since Rothman teaches the connection between 5-HT increase and food craving reduction. Since these compounds are taught to bind to 5-HT_{1a} and Rothman mentions the connection to reduction of food craving, the elements of the invention are all there.

Conclusion

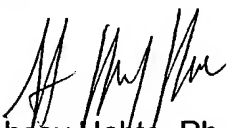
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on (571) 272-0674, if there is no reply for 24 hours, James Wilson (Acting SPE) can be reached at (571)-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624


Mark L. Berch
Primary Examiner
Art Unit 1624

10/15/2004